RECEIVED AT DRUG SAFETY SURVEILLANCE
19-FEB-1998-0708

McN
McNEIL CONSUMER
FORT WASHING

Individual Safety Report
3031799-7-00

Page

A. Patient information

1. Patient identifier	2. Age at time of event: / or Date of birth:	3. Sex	4. Weight
Case 284 in confidence	61 yrs	(X)female ( )male	unk lbs or kgs

B. Adverse event or product problem

1 X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- (X) death: unknown (mo/day/yr)
- ( ) life-threatening
- (X) hospitalization - initial or prolonged
- ( ) disability
- ( ) congenital anomaly
- ( ) required intervention to prevent permanent impairment/damage
- ( ) other:

3. Date of event	4. Date of this report
unknown (mo/day/yr)	02/06/98 (mo/day/yr)

5. Describe event or problem

Case # 284 received from the [redacted] 1996 case fatality data.
See attached case report form provided by [redacted]

6. Relevant tests/laboratory data, including dates

See attached case report form provided by [redacted]

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

See attached case report form provided by [redacted]

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 unknown acetaminophen product
#2 aspirin

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 unknown dose, po	#1 unknown date; 1 day
#2 unknown dose, po	#2 unknown date; 1 day

4. Diagnosis for use (indication)

#1 unknown
#2 unknown

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No (X) N/A

6. Lot # (if known)	7. Exp. date (if known)
#1 Unknown	#1 Unknown
#2 unknown	#2 unknown

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No (X) N/A

9. NDC # - for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)

See attached case report form provided by [redacted]

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-233-7820

3. Report source (check all that apply)

- ( ) foreign
- ( ) study
- (x) literature
- ( ) consumer
- (x) health professional
- ( ) user facility
- ( ) company representative
- ( ) distributor
- ( ) other:

4. Date received by manufacturer (mo/day/yr): 01/30/98

5. [A] NDA # 17-552
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

( ) 5-day (X) 15-day
( ) 10-day ( ) periodic
(X) Initial ( ) follow-up #

8. Adverse event term(s)

OVERDOSE	COMA
HYPERGLYCEMIA	HYPOTENSION
SHOCK	LIVER FUNC ABNO
HEART ARREST	DEATH

9. Mfr. report number: 0929297A

E. Initial reporter

1. Name, address & phone #

[redacted] MD
[redacted] Centers
Suite [redacted] Avenue
[redacted]

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
(X) Yes ( ) No	physician	( ) Yes ( ) No (X) Unk

FDA
Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

[redacted] FATALITY: 1996 [redacted]

Case Number: **284**

Age: 61 yrs

Substances: Aspirin
acetaminophen

Chronicity: Acute

Route: Ingestion

Reason: Int Unknown

Pre-Hospital Arrest? No

This 61 yo female ingested an unknown amount of an unknown substance one to five hours before being found unresponsive. She was taken to a local ED where she arrived comatose. Her initial temperature, vital signs, oxygen saturation and blood pH were all normal. She was given naloxone and flumazenil without response. An NG tube was placed and lavage done without pill return. The poison center was contacted at this time. The patient was noted to have pinpoint pupils and an elevated blood sugar of 246mg/dl. A CT scan of the head was negative. A salicylate level drawn in the ED was 87 mg/dl (2-7 hours post ingestion). The patient was transferred to a tertiary care facility for dialysis.

The patient arrived at the tertiary care facility 4 hours post presentation. Acetaminophen level here was 531 mcg/ml (5.5-11 hours post ingestion). She was started on Mucomyst and underwent dialysis. Salicylate levels dropped to 33 mg/dl after four hours of dialysis. Oral Mucomyst was continued. Shortly after dialysis the patient developed hypotension and cardiogenic shock. This was believed to be due in part to some preexisting cardiac compromise. Liver enzymes became elevated but this was felt to be due more to poor perfusion than acetaminophen toxicity. Despite maximum pharmacologic support, the patient suffered cardiopulmonary arrest unresponsive to code medications and expired 18 hours post presentation (19 to 24 hours post ingestion). The patient's spouse refused the request for an autopsy